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AUTHOR Smith, Terrence; And Others
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ABSTRACT

These three separate pamphlets provide background information, brief discussions of research findings, and guidelines and recommendations concerning selected aspects of diet. The first pamphlet discusses food additives and hyperactivity, focusing on both the Feingold theory and controlled experiments which do not support Feingold's clinical observations and case reports. (The Feingold theory claims that artificial food flavors and colors and antioxidant preservatives cause hyperactivity in genetically predisposed individuals.) The second pamphlet discusses fast food and the American diet as they are related to sound nutritional principles. The third pamphlet, focusing on alcohol use during pregnancy, lists principles and associated features of the fetal alcohol syndrome and presents research findings and recommendations concerning alcohol use during pregnancy. (RH)

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Alcohol Use During Pregnancy

A Report by the American Council on Science and Health

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This report on alcohol use during pregnancy was written by **Terrence Smith, M.P.A.**, ACSH Assistant Director for Research.

The American Council on Science and Health gratefully acknowledges the comments and contributions of the following individuals who reviewed this report:

Roslyn B. Alfin-Slater, Ph.D.*
University of California at Los Angeles

M. A. Benarde, Ph.D.
Hahnemann Medical College and Hospital

Ernest E. Campaigne, Ph.D.
Indiana University

F. M. Clydesdale, Ph.D.
University of Massachusetts

William J. Darby, M.D., Ph.D.
The Nutrition Foundation

William R. Havender, Ph.D.
University of California at Berkeley

Victor Herbert, M.D., J.D.
Bronx Veterans Administration Medical Center
State University of New York

William T. Jarvis, Ph.D.
Loma Linda University

Thomas H. Jukes, Ph.D.*
University of California at Berkeley

Grace Lin, Ph.D.
Rutgers, the State University of New Jersey

Roger P. Maickel, Ph.D.
Purdue University

Kathleen A. Meister, M.S.
American Council on Science and Health

Sheldon I. Miller, M.D.
Cleveland Metropolitan General Hospital

Beverly A. Mosher, M.P.H.
American Council on Science and Health

M. A. Pelosi, M.D.
College of Medicine and Dentistry of New Jersey

Betsy A. Ritz, B.A.
Publications Editor, ACSH

*Dissenting Opinion

David B. Roll, Ph.D.
American Council on Science and Health

Marcia Russell, Ph.D.
Research Institute on Alcoholism

Sidney Shindell, M.D., LL.B.
Medical College of Wisconsin

Fredrick J. Stare, M.D., Ph.D.
Harvard School of Public Health

Judith S. Stern, Sc.D.*
University of California at Davis

John A. Todhunter, Ph.D.
The Catholic University of America

Lyn Weiner, M.P.H.
Boston University School of Medicine

Elizabeth M. Whelan, Sc.D., M.P.H.
American Council on Science and Health

Shahla Wunderlich, Ph.D.
American Council on Science and Health

*Dissenting Opinion

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Introduction

During pregnancy, a woman is faced with many important and sometimes difficult choices. Recent scientific research has identified many so-called "environmental risk factors" that may harm the developing fetus. Several of these risk factors are related to the habits and lifestyle of the mother. One lifestyle factor which is drawing increasing public attention is the use of alcoholic beverages during pregnancy.

Since 1968, a growing body of scientific evidence has shown a relation between alcohol use during pregnancy and the occurrence of spontaneous abortions (miscarriages) and birth defects. In an extreme form these abnormalities are known as the fetal alcohol syndrome (FAS). Some federal and state public health and regulatory officials and private physicians have recently adopted a "no risk" approach to minimize this potential health hazard. Many now advise complete abstention from drinking alcohol during pregnancy. This recommendation contrasts sharply with earlier medical opinions that moderate drinking was harmless, or even good for the expectant mother's mental health. Understandably, many women are confused about which advice is best.

Excessive consumption of alcohol, particularly during pregnancy, is clearly hazardous to health. Total abstinence, of course, will prevent all alcohol-related health problems. But the majority of American women today drink to some extent, and many may wish to continue drinking during pregnancy. Thus, it is important to determine whether there is a level of alcohol consumption that involves little or no risk to the unborn child.

In response to this uncertain issue, the American Council on Science and Health has reviewed the recent scientific evidence on the relationship between alcohol consumption and reproductive effects. This report briefly summarizes the results of both animal and human investigations. It focuses particular attention on the prenatal health effects of alcohol consumption in amounts that many would consider "social" or "moderate" drinking.

Position Statement

The American Council on Science and Health (ACSH) recommends that women be cautious about alcohol use during pregnancy. For those women who choose to drink during pregnancy, ACSH advises that they limit their daily intake to two drinks or less of beer, wine, or liquor. The alcoholic content of two 12-ounce glasses of beer, two 4-ounce glasses of table wine, or two mixed drinks each containing 1½ ounces of 80-proof liquor is approximately the same: each contains about one ounce of 100-percent alcohol.

Although no absolutely safe level of alcohol ingestion has been defined or probably ever will be, the health risks associated with the above level of consumption are apparently low, if they exist at all. These recommendations are intended only as guidelines, as there are substantial differences among women in their ability to tolerate alcohol.

ACSH further recommends that in addition to limiting alcohol use during pregnancy, women should avoid other potential fetal risk factors, particularly cigarette smoking, "recreational" drug use, and poor nutrition.

What is the Fetal Alcohol Syndrome?

The fetal alcohol syndrome (FAS) is a pattern of abnormalities found in some children of women who are chronically alcoholic. The major features of FAS are grouped into four categories as shown in Tables 1 and 2. These include central nervous system disorders and mental retardation, growth deficiencies, facial deformities, and various other abnormalities.

The most obvious features of FAS are the distinctive facial characteristics. FAS children usually have small eye openings (sometimes with "oriental" eye folds) and an underdeveloped midfacial region. The nose is often broad with a low nasal bridge, and the upper lip is narrow with a thin border. The center groove in the upper lip, the philtrum, is usually poorly defined. In some cases, the ears and lower jaw are also malformed.

FAS children have low birth weights and small physical measurements compared with other infants. Their head circumferences (a measure of brain development) and body lengths are often far below those of other children. FAS infants also grow and gain weight very slowly, even with good medical and maternal care. In medical terms, this condition is known as "failure to thrive."

Table 1

Principal Features of the Fetal Alcohol Syndrome

Feature	Symptom
Central Nervous System Disorders	
Intellectual	Mild to severe mental retardation
Neurologic	Small head circumference Poor coordination Lack of muscle tone
Behavioral	Irritability in infancy Hyperactivity in childhood
Growth Deficiencies	
Prenatal	Small birth length Low birth weight
Postnatal	"Failure to thrive" Low proportion of fatty tissue
Facial Characteristics	
Eyes	Small eye openings
Nose	Short, upturned nose
Lips	Underdeveloped upper lip Thin upper lip border
Jaws	Underdeveloped upper jaw Receding lower jaw in infancy Small or protruding lower jaw in adolescence

Perhaps the most important aspect of FAS is the accompanying mental retardation. This retardation is thought to be irreversible, but the severity varies from case to case. Those children who are the most affected physically are also those with the most severe retardation. While some FAS children appear to have relatively normal intelligence scores, others are profoundly retarded and require constant personal care.

In general, FAS children have behavioral problems in addition to their physical and mental disabilities. As infants, they are often irritable and fussy. Older children may be hyperactive and difficult to control in school. One researcher described her FAS patients as "tiny elflike children who were generally hyperactive and poorly focused, with poor attentional skills and poor problem-solving abilities."

Table 2

Associated Features of the Fetal Alcohol Syndrome

Organ	Occurs Frequently	Occurs Occasionally
Eyes	Drooping upper eye lid Crossed eyes "Oriental" eye folds	Near-sightedness Small eyes Small eye openings
Ears	Rotated toward back	Poorly formed ear ridges
Mouth	Prominent ridges in palate	Cleft lip Cleft palate Small teeth with faulty enamel
Heart	Murmurs in early childhood Interior heart wall defects	Chamber wall defects Defects in large blood vessels Tetralogy of Fallot
Kidneys and Genitals	Underdeveloped genitalia	Abnormal urethra in males Small, displaced kidney Obstruction of urinary canal
Skin	Birthmarks	Excess facial and body hair in infancy
Bones	Abnormal creases in palm Sunken breastbone	Limited finger and elbow joint movement Underdeveloped fingernails Extra fingers or toes Fused bones in forearm Abnormal breastbone Abnormal curvature of spine Short neck
Muscles		Hernia of diaphragm, navel, or groin Separation of rectal muscles

The many case studies of FAS in newborns have also reported some similarities among the mothers of these infants. All were known alcoholics at the time they sought prenatal care and all reportedly continued to drink heavily during pregnancy. Many were diagnosed with alcohol-related illnesses such as cirrhosis, delirium tremens (D.T.s), and anemia. However, no information on their

actual drinking habits, particularly in terms of total daily alcohol intake, was recorded in these medical reports.

The mothers of FAS babies are generally around 30 years old with an average seven-year history of alcohol abuse. They have usually had several pregnancies before their FAS child and have had medical problems during labor and delivery. These women are often lighter in weight than other mothers and smoke cigarettes heavily, two factors which are commonly related to alcoholism.

These medical reports have led to theories about the relation between drinking during pregnancy and the occurrence of birth defects and spontaneous abortion. Because some FAS features have been observed in infants of women who were not clearly alcoholic, researchers are also concerned about alcohol's effects at lower, i.e., "social" levels of drinking. They hypothesize that there may be a spectrum of alcohol-related problems ranging from mild to severe. They suspect that the severity of these birth defects is related primarily to the total amount of alcohol consumed during pregnancy.

Historical Perspective

Suspicion about the harmful effects of drinking during pregnancy can be traced back to Biblical times. A passage from the Old Testament Book of Judges states, "Behold thou shalt conceive and bear a son; Now therefore beware, and drink not wine nor strong drink. . . ." Laws in ancient Carthage and Greece also prohibited couples from drinking on their wedding night to prevent conception while intoxicated.

Numerous medical reports in England during the 17th, 18th, and 19th centuries described a link between alcoholic women and the birth of children with a "starved, shriveled and imperfect look." These reports spurred additional research and public interest in the late 19th and early 20th centuries, especially in light of the growth of temperance movements to curb alcohol use. However, the era of Prohibition saw an abrupt end to most alcohol-related research. By the 1940s medical opinion generally dismissed the earlier evidence as unscientific and rejected the idea that alcohol harmed the developing fetus.

This opinion was exemplified by a 1942 British text on alcohol which stated, "The fact is that no acceptable evidence has been offered to show that acute alcohol intoxication has any effect whatsoever on the human germ, or has any influence in altering heredity, or is the cause of any abnormality in the child."

Despite this widespread medical opinion, limited research into the effects of drinking during pregnancy continued. In 1968 a French study reported an increase in the number of children with physical abnormalities, behavioral problems, and mental retardation among families in which the mother, father, or both parents were alcoholic.

In 1973 American researchers from the University of Washington found what they believed to be the first evidence of a relation between alcoholism during pregnancy and the incidence of birth defects. They described a similar pattern of growth deficiencies, facial abnormalities, and other birth defects in eight children from different ethnic backgrounds. After reviewing several more cases, they labeled this pattern of abnormalities the fetal alcohol syndrome (FAS). By 1976 these same researchers had personally evaluated more than 40 children diagnosed with FAS.

More recently, a 1978 review noted that more than 240 cases of FAS have been reported worldwide since 1973. Many other cases of alcohol-related birth defects less severe than the full fetal alcohol syndrome have also been observed. Based on this information, the National Institute on Alcohol Abuse and Alcoholism and the Department of Health and Human Services have estimated that of the known causes of birth defects with accompanying mental retardation, alcohol-related abnormalities may be the third most frequent type, after Down's syndrome (mongolism) and spina bifida, a defect of the spinal column.

Human Studies

To test these theories about the causes of FAS, the National Institute on Alcohol Abuse and Alcoholism has sponsored several studies of large numbers of pregnancies. These epidemiologic studies have been completed or are still in progress in Boston, Seattle, Cleveland, and several California cities. Using statistical analyses, researchers correlate information on the mother's drinking patterns and other habits during pregnancy with any birth defects observed after birth. Because of the complexity of daily life, these epidemiologic studies must take special care to account for those factors which may bias results and conclusions.

One of the most difficult problems facing FAS researchers is accurately measuring individual alcohol consumption. Drinking is a very personal behavior that varies widely. There are large differences in the amount, frequency, and variability of alcoholic beverages individuals consume.

Some may drink a six-pack of beer almost every day, while others may have only an occasional glass of wine. To compound this difficulty, some drinkers, particularly those who want to hide a drinking problem, may under-report their actual drinking habits.

Index of Alcohol Consumption

As a partial solution to this problem, researchers have developed an index of alcohol consumption. Using information voluntarily supplied by the study subjects, the number of drinks of beer, wine, or liquor can be summarized as the average amount of absolute (100 percent) alcohol consumed daily. This index is relatively easy to compute since an average serving of beer, wine, or liquor contains about one-half ounce of absolute alcohol. Thus, one ounce of absolute alcohol daily is roughly equivalent to two 12-ounce cans of beer, two 4-ounce glasses of table wine, or two 1½-ounce portions of 80-proof liquor. However, this averaging method cannot tell whether a person consumed large amounts of alcohol on a few occasions or small amounts on a daily basis. Once again, it is important to remember that not all drinking information supplied voluntarily is accurate.

In addition to the problem of estimating personal alcohol use, epidemiologic studies must take into account other risk factors which may harm the unborn child. Among those that are especially important are cigarette smoking, drug use, and poor nutrition. Since one or more of these risk factors, especially smoking, is often closely related to a woman's drinking habits, epidemiologic studies must try to identify those harmful effects that are due to maternal alcohol use alone.

Results of Human Studies

The results of the human studies generally confirm the damaging effects of abusive alcohol use during pregnancy on fetal growth and development. These studies have found a consistent increase in physical and mental abnormalities, including the full fetal alcohol syndrome, at levels of five or more ounces of absolute alcohol daily. This is equivalent to an average of ten or more daily drinks of beer, wine, or distilled spirits during pregnancy.

Patients at 17 and 2½ years of age with the usual facial appearance observed in the Fetal Alcohol Syndrome.
Reprinted by permission from the *New England Journal of Medicine*, 298:1065-

At the other end of the drinking scale, studies have found no increase in the frequency of physical abnormalities at levels up to one ounce of absolute alcohol, or an average of two drinks, daily. No study can prove an absolutely safe level of drinking. But for this consumption level, the risks, if any, appear low.

The exact relationship between alcohol and birth defects is uncertain for drinking levels during pregnancy between one and five ounces of absolute alcohol daily (2-10 drinks/day). Some studies have found increases in risks of specific types of problems, such as low birth weights, miscarriages, and lowered intelligence scores. But unlike those for higher levels of consumption, these results are not consistent in all studies.

Part of this inconsistency may be explained by the difficulty in measuring personal drinking habits. No common index of consumption was used in all of the studies, and most did not specifically analyze levels between one and five ounces of alcohol daily. Some studies grouped together all those who reported consuming more than an average of two drinks daily. This raises the

possibility that a few very heavy drinkers may have distorted the study results. Studies which focused specifically on this 2-10 drink range found a statistical increase in the number of defects, but of differing types and severity.

Taken as a whole, the epidemiologic evidence for the 2-10 drink range suggests the possibility of increased fetal risks but is not by itself conclusive proof of hazard.

Patients at 1½ and 6 years of age, showing an overall facial appearance differing somewhat from those on page 10.
1066, 1978

Other Contributing Risk Factors

The relationship between alcohol and other possible fetal risk factors has not been completely resolved. No study has yet reported on the effects of the father's drinking habits on conception and fetal development, although several research groups are gathering this type of information. Maternal use of drugs during pregnancy has not been thoroughly considered. In some studies, where medical and behavioral evaluations were made within a short time after birth, the possible short-term effects of painkillers and anesthetics used during labor and delivery may have affected the infant's responses.

In contrast, these studies provide strong evidence that cigarette smoking and alcohol use pose independent risks to the fetus. When these factors are considered separately, heavy drinking or heavy smoking alone can increase the risk of spontaneous abortion and low birth weights. When both habits are combined, as they often are in heavy drinkers, fetal risk is greatly increased.

Poor nutrition during pregnancy may play a secondary role in relation to alcohol use. Those studies which

separately analyzed birth defects in relation to nutritional status found no evidence of FAS-type abnormalities among poorly nourished women who did not drink. One recent study, however, has suggested that nutritional deficiencies related to alcoholism may contribute to the alcohol-related birth defects.

Timing of Alcohol Use During Pregnancy

One other important finding of two of these epidemiologic studies is the relation between the timing of alcohol use during pregnancy and the occurrence of birth defects. During the early stages of pregnancy, when a woman may not know she is pregnant, heavy alcohol use may affect the developing fetal organs and result in malformations. In mid-pregnancy, heavy alcohol use may be related to an increase in the risk of spontaneous abortion. During late pregnancy, when the organs are fully formed and the fetus is growing rapidly in size and weight, alcohol may retard body and brain growth.

The timing of drinking during pregnancy may also be important in another way. Some evidence suggests that binge drinking, the occasional consumption of large amounts of alcohol even by women who usually drink very little, may increase the risk of fetal abnormalities. While this finding requires more study, a drinking binge at a critical time, for example during the first few days or weeks after conception, may result in birth defects that would not have occurred if the same total amount of alcohol was consumed in smaller daily amounts.

The relation between maternal alcohol use and FAS is further complicated by individual differences in the rate at which alcohol is metabolized. Alcohol supplies the body with energy (calories), and women may have individual rates at which alcohol is converted to energy. Alcohol is rapidly absorbed into the blood and crosses the placental barrier into the fetal bloodstream. But due to different metabolic rates, the amount of alcohol that reaches the fetus and the total time of fetal exposure are difficult to determine. Further research is needed to fully study the effects of changing maternal blood alcohol levels on fetal risks.

Animal Studies

Animal studies of alcohol's effects on fetal development are an important complement to the available human evidence. Animal experiments are conducted under strictly controlled laboratory conditions, which eliminates the

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complicating factors of human studies such as determining quantity of alcohol intake, nutritional status, and level of cigarette smoking and drug use. On the other hand, biological differences between animals and humans limit broad interpretations of animal test results.

Statistical problems also limit the use of animal studies in estimating human risk. The animal studies of alcohol conducted thus far have employed small numbers of test animals. Because birth defects from all causes are relatively rare, studies using only a few animals may fail to find any malformations. Studies in which alcohol is injected rather than given orally are also harder to interpret. Despite these and other limitations, recent animal tests have generally confirmed certain harmful effects of relatively high doses of alcohol on fetal development.

Abnormalities in Offspring

Using rats, mice, rabbits, beagle dogs, and miniature swine, researchers have found an increased number of birth defects, growth problems, and behavioral changes in the offspring of alcohol-treated animals. The abnormalities include stillbirths, low birth weights, and a variety of physical defects in offspring. In several studies, the abnormalities were similar to those observed in human FAS infants.

The observed increases in birth defects were found in some studies at levels equivalent to high, but not necessarily abusive, levels of human alcohol consumption. In rats, mice, and miniature swine (which voluntarily drink large amounts of alcohol) abnormalities were found at a level equivalent to six to eight drinks daily. This amount corresponds to three to four ounces of absolute alcohol per day. Other experiments with mice and beagles have shown an increase in birth defects at dose levels greater than the human equivalent of six ounces of absolute alcohol daily.

Animal studies have also provided support for the relationship between the timing and duration of maternal alcohol use and fetal abnormalities. In one experiment which used mice to study the effects of "binge drinking," the number of fetal deaths increased when large doses of alcohol were given on certain days following conception. In another study using miniature swine, a greater number of defects occurred among the offspring whose mothers were exposed to alcohol for the longest periods of time. This finding is similar to the human clinical reports which described mothers of FAS infants as generally older with a long history of alcohol abuse.

One study using two different strains of laboratory mice showed the importance of genetics and the mother's metabolic processes in relation to fetal defects. One strain of mice had more defects than the other even though both groups of test animals were given the same doses of alcohol. These results illustrate that alcohol metabolism is largely controlled by heredity, a fact which must be taken into account along with the total amount and frequency of drinking in human mothers.

Importance of Blood Alcohol Levels

Animal studies have shown that blood alcohol levels are more important than the amount of alcohol consumed in terms of fetal risk. Unfortunately, the option of measuring blood alcohol levels in humans is generally not available to epidemiologists since most pregnant women who participate in epidemiologic studies would probably be unwilling to submit to daily blood sampling.

In general, the animal studies so far appear to discount the possibility that some other risk factor is responsible for the observed birth defects. They have shown that alcohol alone is related to an increase in the number of physical abnormalities and stillbirths. These studies do not completely dismiss nutritional effects or interactions between alcohol and nutritional deficiencies.

Even if there were no human evidence, the results of these animal studies would strongly suggest the need for additional research. When the body of human and animal evidence is viewed as a whole, the adverse health risks posed by abusive levels of alcohol use are clear. However, the minimum level of alcohol consumption which subjects the fetus to risk is unknown.

Drinking Patterns in the United States

The use of alcoholic beverages is a part of the lifestyle of many American adults. The majority drink to some extent and consume a wide variety of alcoholic beverages. During the past ten years, per capita alcohol consumption has maintained its highest level since 1850. In the U.S., yearly per capita consumption by those 14 years and older is estimated at 2.6 gallons of absolute (100 percent) alcohol. This figure does not take into account waste or loss and is therefore likely to overestimate actual consumption.

When the fetal alcohol syndrome was first described in 1973, the need for more detailed knowledge about women's drinking habits increased. National surveys have estimated the proportions of women whose drinking behavior falls into different groups.

In these surveys, heavy drinkers are defined as those who consume at least two drinks (one ounce of absolute alcohol) daily. This group includes those who regularly have two or more drinks as well as those who have occasional or frequent drinking binges. Light drinkers are those who drink more than once a year, but usually no more than one or two drinks at a time. Moderate drinkers are those who fall between these two extremes. Moderate drinkers generally consume smaller total amounts of alcohol than heavy drinkers, but may also have an occasional drinking binge. It is important to note, however, the differences between these descriptions based on drinking surveys and those most people would use to describe personal drinking habits. For example, a person who drinks three cans of beer (1½ ounces absolute alcohol) daily probably doesn't regard this as "heavy" drinking.

The most recent survey of drinking practices among women estimates that about 57 percent of all women over age 18 drink at least once a year. Of these, 4 percent are heavy drinkers, 16 percent moderate drinkers, and 37 percent light drinkers. Forty-three percent are abstainers.

Applying these estimates to the 1977 population as shown in Table 3, approximately 44 million women drink at least once a year. Among these, about 3 million are heavy

Table 3

Number of U.S. Females Age 18+ by Drinking Category, 1977

Category	Percent	Number
All Females Age 18+	100	76,886,000
Abstainers	43	33,061,000
Light	37	28,448,000
Moderate	16	12,302,000
Heavy	4	3,075,000

drinkers who consume at least two drinks, or one ounce of absolute alcohol daily. This heavy drinking group includes those women who are alcoholics as well as those who are regular, but not abusive, drinkers. The moderate drinking category, which may also include some number of binge

drinkers, totals about 12 million women. Approximately 28 million women are light or infrequent drinkers. Thirty-three million women over age 18 are abstainers.

These drinking surveys have also found that drinking habits among women vary with a number of personal characteristics. Age, race, religion, education level, socioeconomic status, and ethnic background all have an impact on personal drinking patterns. For example, an increase in drinking is found among young women, whites, those with some college education, the middle class, and those with an ethnic background from countries in Europe. In contrast, there is a lesser tendency to drink among older women, blacks, Orientals, and those with less than a high school education or low economic status.

Drinking during Pregnancy: Summary

In 1973, researchers "rediscovered" a long suspected relationship between maternal alcoholism and the birth of abnormal infants. Since then, evidence from human and animal studies has clearly demonstrated the harmful effects of abusive drinking on the unborn child. For alcohol consumption in the range of two to ten drinks daily, the evidence of increased health risks is suggestive, but not conclusive.

The Department of the Treasury and the Bureau of Alcohol, Tobacco and Firearms (BATF) announced in 1979 a program to educate women about the risks of alcohol use during pregnancy. These agencies recommend that women completely abstain from drinking alcoholic beverages during pregnancy. In 1981, the Surgeon General's Advisory on Alcohol and Pregnancy made the same recommendation. This advice is based on the judgment that no "safe" level of drinking during pregnancy has been proven and that there is little evidence of any benefits of drinking for the mother or child.

ACSH's review of the literature does not support the contention that abstinence from alcohol is necessary to protect the health of the fetus. While it would be easier to recommend that expectant mothers avoid all alcoholic beverages, ACSH is concerned that excessive health warnings may be counterproductive, leading pregnant women to equate real risks during pregnancy (for example, cigarette smoking) with hypothetical risks (moderate use of alcohol). ACSH believes that health warnings should be issued only when there is scientific evidence to support them.

Furthermore, ACSH feels that public health scientists ought to be aware of the possible ramifications of their warnings and statements. A woman may unnecessarily worry about having had a drink or two each day before her pregnancy was confirmed. Ultimately she might consider the option of abortion, fearing the birth of a deformed child when actually there is no scientific evidence for such concerns.

The American Council on Science and Health supports a national program to educate women about the possible adverse effects of excessive drinking during pregnancy. Based on the current evidence, women should take a conservative approach to alcohol use during pregnancy. No evidence from any animal or human study has found a substantial risk to the unborn child from consumption of less than one ounce of absolute alcohol (two average drinks) per day. Yet as noted earlier, neither has this amount been proven to be safe.

As a result of its review of the scientific evidence, the American Council on Science and Health recommends that during pregnancy a woman should:

- Discuss with her physician the risks of drinking, smoking, drug use, poor nutrition, and other potentially hazardous factors during pregnancy. Ideally, this should be done before pregnancy.

- Limit consumption of alcohol to no more than two drinks daily. This limit of one ounce of absolute alcohol daily is equivalent to two 12-ounce glasses of beer, two 4-ounce glasses of wine, or two mixed drinks each containing 1½ ounces of 80-proof liquor.

- Avoid substituting other drugs for alcohol to relieve tension or anxiety since some drugs may have significant risks of their own.

- Particularly avoid "binge" drinking.

Dissenting Opinion

We support the recommendations of the Department of the Treasury, the Bureau of Alcohol, Tobacco and Firearms, and the Surgeon General that women not drink alcoholic beverages during pregnancy.

Some of the problems of alternative recommendations are as follows:

1. The threshold of adverse effects of alcohol on human fetuses is unknown.
2. Individual variations in the threshold would undoubtedly occur. Some fetuses might be inordinately sensitive to alcohol.
3. The amount of alcohol in mixed drinks is not standardized, and under conditions of social drinking, is highly variable.

Undoubtedly, there is a level of alcohol intake, as yet undetermined, that is not hazardous during pregnancy. Probably an occasional glass of beer or wine is tolerable in pregnancy, just as in the case of driving an automobile, provided that "one drink does not lead to another." Total prohibition of drinking is an unacceptable rule for many people. Nevertheless, we believe that many pregnant women will prefer to give up drinking "for the duration."

Thomas H. Jukes, Ph.D.
Professor in Residence, Biophysics and Medical Physics
Lecturer in Nutritional Sciences
University of California at Berkeley

Roslyn B. Alfin-Slater, Ph.D.
Professor of Nutrition, School of Public Health
Professor of Biochemistry, School of Medicine
University of California at Los Angeles

Judith S. Stern, Sc.D.
Associate Professor
Department of Nutrition
University of California at Davis

American Council on Science and Health

1995 Broadway
(near 68th Street)
New York, NY 10023
Telephone: 212 362 7044

1111 19th Street, N.W.
Suite 301
Washington, DC 20036
Telephone: 202 659 8978

Dr. Elizabeth M. Whelan
Executive Director

47 Maple Street
Summit, NJ 07901
Telephone: 201 277 0024

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New York, New York

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University of Florida
Nutritionist, Food Scientist

Stephen Barrett, M.D.
Lehigh Valley Committee Against
Health Fraud, Inc.
Phychiatrist, Leader in Combating
Health Quackery

M. A. Benarde, Ph.D.
Hahnemann Medical College and Hospital
Epidemiologist, Environmental Specialist

Norman Borlaug, Ph.D.
International Center for Maize and
Wheat Improvement
Agricultural Technologist
Nobel Laureate

Ernest J. Bristay, Ph.D.
Oregon State University
Agricultural Biochemist

John M. Buchanan, Ph.D.
Massachusetts Institute of Technology
Biochemist

John P. Callan, M.D.
Hartford, Connecticut
Psychiatrist, Media Specialist

Ernest E. Campaigne, Ph.D.
Indiana University
Organic Chemist

F. M. Clydesdale, Ph.D.
University of Massachusetts
Food Technologist, Nutritionist

Julius M. Coon, M.D., Ph.D.
Jefferson Medical College
Pharmacologist, Toxicologist

Chester E. Cross, Ph.D.
University of Massachusetts
Agricultural Technologist

T. J. Cunha, Ph.D.
California State Polytechnic University
Animal Nutritionist, Livestock Specialist

Robert M. Devlin, Ph.D.
University of Massachusetts
Plant Physiologist

J. Gordon Edwards, Ph.D.
San Jose State University
Entomologist

Morril Eisenbud, Sc.D.
New York University Medical Center
Specialist in Environmental Health

Dean C. Fletcher, Ph.D.
Washington State University
Nutritionist, Toxicologist
Cancer Researcher

E. M. Foster, Ph.D.
University of Wisconsin
Food Microbiologist

F. J. Francis, Ph.D.
University of Massachusetts
Food Technologist

Roger E. Gold, Ph.D.
University of Nebraska
Entomologist

W. Grierson, Ph.D.
University of Florida
Plant Physiologist

22

Alfred E. Harper, Ph.D.
University of Wisconsin
Biochemist

William R. Havender, Ph.D.
University of California at Berkeley
Research Biochemist

William E. Haustetine, Ph.D.
Butte County California Mosquito
Abatement District
Manager, Environmentalist, Entomologist

Victor Herbert, M.D., J.D.
Bronx Veterans Administration
Medical Center
State University of New York
Internist, Hematologist, Nutritionist
Attorney

William T. Jarvis, Ph.D.
Loma Linda University
Consumer Health Specialist

Thomas H. Jukes, Ph.D.
University of California at Berkeley
Biochemist, Nutritionist
Molecular Evolutionist

Paul E. Kilgor, Ph.D.
Oregon State University
Food Technologist, Nutritionist

James R. Kirk, Ph.D.
University of Florida
Nutritionist

Stephen M. Kraitzman, Ph.D.
Emory University
Nutritionist

Manfred Kroger, Ph.D.
Pennsylvania State University
Food Scientist

J. Clayborn LaForce, Ph.D.
University of California at Los Angeles
Economist

Robert MacVicar, Ph.D.
Oregon State University
Agricultural Biochemist

Roger P. Maickel, Ph.D.
Purdue University
Pharmacy and Pharmacal Sciences
Specialist

Nancy G. Manno, J.S.D.
Emory University
Economist, Attorney

Kristen McNutt, Ph.D.
University of Illinois
Medical Center
Nutritionist

Joseph M. Miller, M.D.
New Hampton, New Hampshire
Physician, Health Consultant

J. E. Oldfield, Ph.D.
Oregon State University
Animal Specialist

Robert E. Olson, M.D., Ph.D.
St. Louis University Medical School
Clinical Nutritionist

Richard E. Partch, Ph.D.
Clarkson College
Synthetic and Physical Organic Chemist

Sheva Rapoport, D.D.S.
American Dental Association
Periodontal Dentist, Consumer Advisor

Ewald B. Relf, Ph.D.
American Council on Science and Health
Medicinal Chemist

Paul Saltman, Ph.D.
University of California at San Diego
Biochemist

B. S. Schweigert, Ph.D.
University of California at Davis
Food Scientist

Sidney Shindell, M.D., LL.B.
The Medical College of Wisconsin
Specialist in Preventive Medicine
and Occupational Epidemiology

Sarah H. Short, Ph.D., Ed.D.
Syracuse University
Nutritionist, Educational and
Media Specialist

Henry F. Smyth, Jr., Ph.D.
University of Pittsburgh
Industrial Toxicologist

Robert R. Spitzer, Ph.D.
Milwaukee School of Engineering
Agricultural Technologist

Frederick J. Stare, M.D., Ph.D.
Harvard School of Public Health
Physician, Nutritionist

Judith S. Stern, Sc.D.
University of California at Davis
Nutritionist

Stephen S. Sternberg, M.D.
Memorial Sloan-Kettering Cancer Center
Pathologist

Stanley E. Walker, Ph.D.
University of Nebraska
Food Technologist, Food Scientist

Elizabeth M. Whelan, Sc.D., M.P.H.
American Council on Science and Health
Public Health Specialist

Philip L. White, Sc.D.
American Medical Association
Nutrition Educator

W. L. Williams, Ph.D.
University of Georgia
Research Biochemist

Richard Wilson, Ph.D.
Harvard University
Energy and Environmental Specialist

Warren Winkelstein, Jr., M.D.
University of California at Berkeley
Physician, Epidemiologist

James H. Young, Ph.D.
Emory University
Social Historian, Medicine

John A. Zapp, Jr., Ph.D.
Kennett Square, Pennsylvania
Toxicologist, Industrial Hygienist

Policy Advisors

S. John Byington, J.D.
Rogers Hoge & Hills, P.C.
Attorney, Former Chairman
Consumer Product Safety Commission

John Diebold
The Diebold Group, Incorporated
Management Consultant

Joseph F. Murphy, LL.B.
LeBoeuf, Lamb, Leiby & MacRae
Attorney

Fast Food and The American Diet

A Report by the
American Council
on Science and Health

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ACSH gratefully acknowledges the comments and contributions of the following individuals who reviewed this report:

Howard Appledorf, Ph.D.
University of Florida

Stephen Barrett, M.D.
Lehigh Valley Committee Against Health Fraud, Inc.

Melvin A. Benarde, Ph.D.
Hahnemann Medical College and Hospital

Ruth Carol, Ed.D.
American Council on Science and Health

F.M. Clydesdale, Ph.D.
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State University of New York

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Loma Linda University

Paul E. Kifer, Ph.D.
Oregon State University

James R. Kirk, Ph.D.
University of Florida

Manfred Kroger, Ph.D.
Pennsylvania State University

Robert MacVicar, Ph.D.
Oregon State University

Kathleen A. Meister, M.S.
American Council on Science and Health

Joseph M. Miller, M.D., M.P.H.

J.E. Oldfield, Ph.D.
Oregon State University

Robert E. Olson, M.D., Ph.D.
St. Louis University School of Medicine

Betsy A. Ritz, B.A.
American Council on Science and Health

David B. Roll, Ph.D.
American Council on Science and Health

Paul D. Saltman, Ph.D.
University of California at San Diego

B.S. Schweigert, Ph.D.
University of California at Davis

Sidney Shindell, M.D., LL.B.
The Medical College of Wisconsin

Sarah Short, Ph.D., Ed.D., R.D.
Syracuse University

Terrence Smith, M.P.A.
American Council on Science and Health

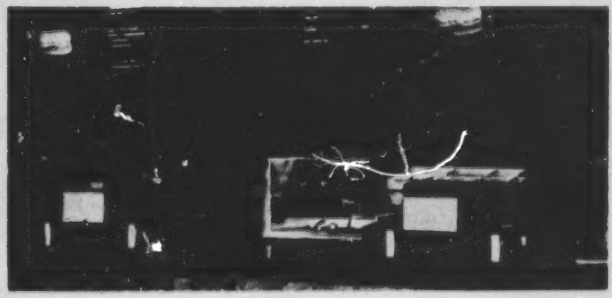
Fredrick J. Stare, M.D., Ph.D.
Harvard School of Public Health

Judith S. Stern, Sc.D.
University of California at Davis

John A. Todhunter, Ph.D.
The Catholic University of America

Stanley E. Wallen, Ph.D.
University of Nebraska, Lincoln

Elizabeth M. Whelan, Sc.D., M.P.H.
American Council on Science and Health



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Introduction

Judging from its tremendous sales growth over the last ten years, fast food has assumed a major role in American life. And yet, it makes some of us uneasy. We love those double cheeseburgers, fries, and shakes, those pizza supremes and those fried chicken dinners. But are these meals nutritionally sound?

The American Council on Science and Health has prepared this report to discuss some of the concerns about the nutritional value of fast foods. This report will present information on the nutrient content of various types of fast food and will describe the actual and potential nutrient contributions of fast food meals to the daily diet.

Position Statement

"Fast food" may be defined as relatively low-cost food purchased at an outlet featuring quick service and convenience. It might be described more accurately as "fast-service food," because it is the speed and style of service, rather than the food itself, which distinguishes fast food restaurants from others.

Contrary to common belief, fast food is not nutritionally worthless. In fact, its potential nutritional contribution to the diet is limited only by the variety of menu items available. This variety has widened from the original hot dog/hamburger/fried chicken meals to include pizza, Mexican foods, roast beef sandwiches, seafoods, and other items. Recent additions to some fast food menus include soup and salad bars and breakfasts.

Consumers who want to eat healthfully can incorporate fast food meals into a balanced diet by varying their fast food selections and by choosing meals of appropriate calorie content. Individuals who must restrict their intake of calories, sodium, or cholesterol need to be aware of the nutritional composition of fast food menu items in order to choose meals that are compatible with their special needs.

The key to wise use of fast food—and all foods—is selection in accordance with sound nutrition principles. Moderation, variety, and a balance of items from the Basic Four Food Groups (breads/cereals, fruits/vegetables, dairy products, and the meat group, which also includes poultry, fish, eggs, and legumes) are the foundations of a healthful diet. As more consumers incorporate these nutrition principles into their eating patterns, we may see an increased demand for variety and opportunities to exercise moderation at fast food restaurants, a demand to which the industry would undoubtedly respond.

Fast Food: A Booming Industry

The growth of the fast food industry over the past 25 years has been phenomenal. Between 1970 and 1980 fast food sales increased by more than 300 percent, from $6.5 billion to $23 billion annually. There are now over 140,000 fast food outlets nationwide, compared to 30,000 in 1971, and more than 300 regional and national restaurant chains.

The fast food industry must credit much of its success to post-World War II technology. Improved farming methods have allowed increased food production at lower cost. New methods of processing, preserving, and transporting food, as well as the development of specialized equipment, have simplified restaurant operation. Not only is food prepared speedily, it is usually of high quality.

Who Eats Fast Food, How Often, and Why?

The popularity of fast food is well-documented. A 1978 consumer survey showed that in one six-month period, 90 percent of Americans ate in a fast food restaurant at least once. Most fast food consumers eat between one and three fast food meals a week. Ten percent eat fast food more than five times weekly.

Americans over age 35 remember when "eating out" was a special occasion. Those under 35, on the other hand, can barely recall life without fast food and are its ardent fans. Young families with three or more members patronize fast food restaurants most frequently. As family income increases, fast food consumption also increases, through the upper-middle class level.

Fast food is one part of today's less formal, often hectic lifestyle. As women spend more time working at jobs outside the home, they may have less time to devote to food preparation. In many families, husbands and children no longer expect their wives/mothers to be responsible for cooking, and conflicting activity schedules often make it difficult to plan family mealtimes. Fast food is a convenient alternative in these situations. Increases in disposable income, leisure time, and travel have boosted the popularity of restaurant dining in general and fast food in particular.

Between 1960 and 1973 average family expenditures on food prepared in restaurants and take-out stands doubled.

Surveys suggest that nutritional quality is not a primary concern of consumers when they select a fast food restaurant. At the present time, the majority of customers regard taste, price, and convenience as more important factors in choosing fast food.

Cheaper than Eating at Home?

The relatively low cost of fast food is one of its prime attractions. Nationally, the average price of a fast food meal in 1975 was $2.85, compared to $6.92 in a conventional restaurant.

Sixty-three percent of the respondents to a 1977 Nielsen survey believed that the cost of eating at a fast food restaurant was the same or less than the cost of eating at home. Fast food is actually more expensive than its home-prepared counterpart, however, if no value is set on domestic labor and overhead costs. Fast food hamburgers and cheeseburgers cost 25-33 percent more than homemade items, and pizza costs twice as much. An entire fast food meal, including entree, fries, soft drink or shake, and dessert, will usually cost twice as much as the same meal prepared at home.

Can Fast Food Be Part of a Healthful Diet?

It is possible to eat healthfully at fast food restaurants, just as it is possible to do so at home. In either case, the consumer must know some basic nutrition rules and apply them.

A healthful diet should include a variety of foods chosen from the Basic Four Food Groups and eaten in quantities appropriate to the individual's energy (calorie) needs. Adults should choose daily four or more servings from the breads/cereals group, four or more servings from the fruits/vegetables group, two or more servings from the dairy products group (children need four servings) and two or more servings from the meat group. Serving sizes should be adjusted to match calorie needs. Adherence to these rules helps to ensure adequate daily nutrient intake.

Nutrients in Fast Food

The following sections will present a summary of the nutrient content of different kinds of foods served by several national fast food restaurant chains. A more complete nutrient analysis of selected fast foods can be found in the Appendix on page 12.

This discussion will refer several times to Recommended Dietary Allowances, or RDA. These are recommended levels of daily intake of essential nutrients established for various sex-age groups by the Food and Nutrition Board of the National Academy of Sciences.

Nutrient requirements differ among individuals. RDA are not the same as minimum requirements, and are set at levels considered adequate to meet the known nutritional needs of practically all healthy people.

For nutrition labelling of foods, a simplified set of standards, derived from the RDA, are used. These standards, called the U.S. RDA (U.S. Recommended Daily Allowances), are described in more detail in the appendix to this report.

Protein

An ample supply of protein is essential for good health. Most people in this country consume more than adequate amounts of this nutrient. Animal products such as fish, chicken, beef, cheese, and milk are excellent protein sources and are available in all fast food restaurants. Even a small hamburger supplies 25 percent of the RDA for protein of an adult man, and 33 percent of a woman's or child's protein RDA. By choosing a larger hamburger, topping it with cheese, or ordering a shake, it is possible to fulfill 60 to 100 percent of one's protein RDA with a single fast food meal.

Fat

There is no specific RDA for fat, although a balanced diet should include some fat, as well as protein and carbohydrate. Some of the major components of fast food (beef, cheese, mayonnaise) and one popular method of cooking (deep fat frying) are rich sources of fat. Many consumers are unaware that all meat, even lean meat, contains substantial amounts of fat, as well as protein.

Because fat is calorically dense, too much fat in the diet can be a problem. The same amount of fat, by weight, supplies slightly more than twice as many calories as either protein or

carbohydrate. People who need to limit their calorie intake would be well-advised to limit their consumption of high fat/high calorie foods.

Carbohydrates and Fiber

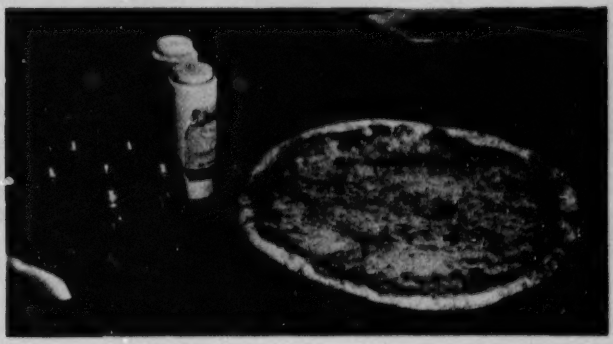
A well-balanced diet should include digestible carbohydrates (starches and sugars) as well as protein and fat. There is no specific RDA for carbohydrate. Many nutrition experts have suggested, however, that intake of complex carbohydrates (starches) should be maintained at current levels or even increased. At fast food restaurants, carbohydrates come in the form of enriched rolls, french fries, shakes, soft drinks, and desserts. Starch is the major carbohydrate in rolls and french fries; sugar predominates in the other items. French fries, because they are deep fat fried, also provide substantial amounts of fat.

The Food and Nutrition Board of the National Academy of Sciences has suggested that some Americans should increase moderately their intake of foods high in dietary fiber, the indigestible material that some people call roughage. Fiber is found primarily in fresh fruits and vegetables and in whole grain breads and cereals. Fast food menu items are generally low in fiber, except for salads and cole slaw, which are recent additions to many fast food menus.

Calories

The calorie count of fast food meals varies according to the size and number of items chosen. A meal of a hamburger (with roll, as served) and a diet soft drink provides only 270 Calories, a meal of a quarter-pound hamburger, fries, and shake provides more than 1000 Calories. People who must limit their calorie intake should be careful about the choices they make in fast food restaurants, since the menus include many high-calorie items. On the other hand, meals which are high in calories are appropriate for physically active individuals with high energy needs. Individuals with lower calorie needs may choose less caloric menu items, eliminate high-calorie toppings such as mayonnaise, choose *fewer* items, or limit calories in other meals. Consumers who need to restrict calorie

intake should become familiar with the calorie counts of their favorite fast food items. With such knowledge in hand, fast food can even be incorporated into a weight-reduction diet!



Vitamins

The B-complex vitamins are found in almost all foods in varying amounts. Most fast food meals provide adequate amounts of thiamin (vitamin B_1), riboflavin (vitamin B_2), and niacin, as well as vitamin B_6 (pyridoxine) and vitamin B_{12} (cobalamin).

Vitamin C is found primarily in citrus fruits and some vegetables. Good sources of this vitamin on the fast food menu include orange juice (available in many outlets that serve breakfast), cole slaw, and the increasingly common salads. There is also vitamin C in potatoes. Some of this vitamin is lost, however, during the processing and cooking of potato products such as french fries.

Traditional hamburger or chicken fast food meals are low in vitamin A, the best sources of which are dark green leafy vegetables, dark yellow (orange) vegetables and fruits, whole milk, fortified nonfat dairy products, and organ meats such as liver. Mexican-style foods and pizza provide some vitamin A from tomatoes and cheese. Salads usually include raw carrots and tomatoes which also provide vitamin A.

Minerals

Shakes and milk are available in most fast food outlets and are high in calcium and phosphorus. Hamburgers are an excellent source of iron, and rolls made with enriched flour are a fair source of this mineral. Beef and dairy products, used in many fast food entrees, are good sources of zinc.

Individuals who are under a physician's orders to reduce their sodium intake (common advice to people who have high blood pressure) should be aware that many fast foods are relatively high in sodium due to their high content of salt (sodium chloride). It may be impossible to fit some menu items into sodium-restricted diets. Information on the sodium content of many specific menu items is included in the Appendix to this report.

Condiments such as pickles, catsup, and mustard also contain substantial amounts of sodium. Consumers who add salt to fast food items before eating further increase the food's sodium content.

The Overall Nutrition Picture

Fast food's best nutritional feature is undoubtedly its protein content. Many fast food items also provide vitamins and minerals in moderate to large quantities. The addition of salads to fast food menus has increased the available sources of vitamins A and C and dietary fiber.

A nutritional drawback of fast foods, particularly for frequent consumers, is the limited number of items on many fast food restaurant menus. The broader selection of items that some chains are beginning to offer is a step in the right direction, because variety is important for good nutrition. Meals eaten at fast-service restaurants should be incorporated into a varied diet that includes many other food choices.

Since many fast food items are quite high in calories and sodium, individuals on restricted diets must plan their fast food choices carefully. Salads are often good choices in such cases as long as the salad dressing is chosen with its sodium and/or calorie content in mind.

The Impact of Fast Food on the Diet

In order to assess the nutrient contribution of fast food to the diets of fast food consumers, a group of researchers in 1976 interviewed 280 patrons of a national hamburger chain. Interviews were conducted at two different restaurants, one which was frequented primarily by college students and one which was visited by a larger number of older adults. Fifty-two percent of the patrons interviewed considered their purchases complete meals, rather than snacks. These meals were analyzed for nutrient content using data provided to the company by an independent commercial laboratory, which had carefully analyzed the menu items for several important nutrients. The analysis showed the following:

The average Calorie count of meals was 685 at the location visited mostly by students and 630 at the other restaurant. Only one-quarter of those purchasing meals received more than one

third of their RDA for energy (calories). The RDA for energy, which is measured in calories, is set at a level which meets the needs of the *average* member of a particular sex-age group. Unlike the other RDA, it is not set at a level high enough to meet the needs of practically everybody, since that kind of recommendation would encourage overeating. Calorie requirements differ greatly among individuals, varying particularly with level of physical activity, and also with body size and other factors. An individual's calorie needs may be greater or less than the RDA, but the RDA is useful for analyzing data about groups of people, like the fast food consumers in this survey.

The survey results suggest that many people watch their calorie intake when eating at fast food restaurants, and keep it moderate.

Patrons who regarded their purchases as snacks rather than meals consumed an average of 427 Calories at the restaurant visited mainly by students and 282 Calories at the other location. People's needs for calories decrease as they get older. This finding suggests that older people with declining energy requirements decreased the sizes of their snacks at fast food restaurants.

Ninety percent of the patrons who regarded their purchases as meals obtained one fourth or more of their protein RDA; 77 percent obtained one third or more.

Fifty-five percent of the meals provided one fourth or more of the individual's RDA for vitamin C. If this figure seems high, it is because some patrons were surveyed at the breakfast hour when orange juice was served. Fifty-one percent of the meals provided one fourth or more of the thiamin RDA; 36 percent provided one fourth or more of the RDA of iron; and 28 percent provided one fourth or more of the calcium RDA. Vitamin A was the only nutrient studied that was consistently low. The restaurants surveyed did not have salad bars.

These survey results suggest that even at a limited menu restaurant, substantial amounts of many nutrients are readily available. Consumers who vary their fast food choices can obtain a significant portion of their daily nutrient needs from fast food meals, and they can and do choose meals that are not excessively high in calories.

Where to Get Nutrition Information on Fast Food

Most fast food restaurant chains will supply consumers with nutrition information. Some companies also have nutrition specialists or food technologists at their corporate or research headquarters who can and do answer specific questions about the nutrient content of the company's products. Individual restaurants rarely have nutrition information on hand, but consumers can obtain this information by writing to the following addresses.

Arby's Inc.
Consumer Affairs
One Piedmont Center
3565 Piedmont Road, NE
Atlanta, Georgia 30305

Burger Chef Systems, Inc.
College Park Pyramids
P.O. Box 927
Indianapolis, Indiana 46206

Burger King Corporation
Consumer Information M/S 1441
P.O. Box 520783
Miami, Florida 33152

Jack in the Box
9330 Balboa Ave.
San Diego, California 92123

Kentucky Fried Chicken
Consumer Affairs Department
P.O. Box 32070
Louisville, Kentucky 40232

(Long John Silver's)
Jerrico, Inc.
Food and Beverage Department
P.O. Box 11988
Lexington, Kentucky 40579

McDonald's Corporation
Consumer Affairs
McDonald's Plaza
Oak Brook, Illinois 60521

Pizza Hut, Inc.
Consumer Affairs Department
9111 E. Douglas
P.O. Box 428
Wichita, Kansas 67201

Wendy's International, Inc.
Consumer Affairs Department
4288 West Dublin Granville Road
P.O. Box 256
Dublin, Ohio 43017

FISH											
Long John Silver's®											
Fish (2 pieces)	366	22	22	21	NA	NA	40	NA	NA	NA	NA
McDonald's®											
Filet-O-Fish®	402	15	23	34	710	43	35	2	6	10	10
CHICKEN											
Kentucky Fried Chicken®											
Original Recipe® Dinner	830	52	46	56	2285	285	115	15	45	15	25
Extra Crispy Dinner	950	52	54	63	1915	265	115	15	45	15	20
(Dinners contain 3 pieces chicken, mashed potatoes, gravy, cole slaw, and roll.)											
PIZZA											
Pizza Hut®§											
Standard Cheese (½ 13" medium, Thin 'N Crispy®)	680	38	22	84	1800	NA	80	24	*	100	40
Supreme (½ 13" medium, Thin 'N Crispy®)	800	42	34	88	2400	NA	90	30	8	80	50
SHAKES											
McDonald's®											
Chocolate	364	11	9	60	320	29	25	6	*	35	6
Jack in the Box®											
Strawberry	380	11	10	63	268	33	25	8	*	35	2
Burger Chef®											
Vanilla	380	13	10	60	NA	34	30	8	*	50	2
COLE SLAW											
Long John Silver's®	138	1	8	16	NA	NA	2	NA	NA	NA	NA
FRENCH FRIES											
McDonald's®											
Regular	210	3	11	26	115	10	4	*	20	*	2
Jack in the Box®	270	3	15	31	130	13	4	*	6	2	4

NA—data not available

*less than 2 percent

†The U.S. RDA (U.S. Recommended Daily Allowance) is the standard used for nutrition labelling and is meant to apply to almost all Americans 4 years of age and older. It is derived from the RDA (Recommended Dietary Allowances) described in the text of this report by using the RDA for the sex-age group which has the *highest* nutrient requirement. For most nutrients, this group is teenage boys. (Pregnant and lactating women are not included. They, infants, and children under the age of 4 are covered by separate U.S. RDAs.)

‡The U.S. RDA for high quality protein (such as that found in eggs and other animal products) is 45 grams, and for lower quality protein (found in vegetable sources) is 65 grams.

§PIZZA HUT and THIN 'N CRISPY are registered trademarks of Pizza Hut, Inc., and are being use with permission. Data derived from a 1979 analysis of Pizza Hut products.

Food Additives and Hyperactivity

A Report by the American Council on Science and Health

PS 013016

Food Additives and Hyperactivity

This report on food additives and hyperactivity was prepared by the staff of the **American Council on Science and Health** (ACSH). It is based on research compiled by ACSH Research Associates **Margaret J. Sheridan, M.S., R.D.**, and **Kathleen A. Meister, M.S.** A technical summary of this research has also been published. (Stare, F.J., E.M. Whelan, and M.J. Sheridan, "Diet and hyperactivity: Is there a relationship?" *Pediatrics* 66:521, 1980.)

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ACSH gratefully acknowledges the comments and contributions of the following individuals who reviewed this report.

Roslyn B. Alfin-Slater, Ph.D.
University of California at Los Angeles

Stephen Barrett, M.D.
Lehigh Valley Committee Against Health Fraud, Inc.

Melvin A. Benarde, Ph.D.
Hahnemann Medical College and Hospital

John M. Buchanan, Ph.D.
Massachusetts Institute of Technology

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Syracuse University

Fredrick J. Stare, M.D., Ph.D.
Harvard School of Public Health

Stanley E. Wallen, Ph.D.
University of Nebraska, Lincoln

Esther H. Wender, M.D.
University of Utah

Elizabeth M. Whelan, Sc.D., M.P.H.
American Council on Science and Health

Philip White, Sc.D.
American Medical Association

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Introduction

Between five and ten percent of all school-age children in the United States have been labeled "hyperactive." In medical terminology, their condition is called hyperkinesis or "attention deficit disorder" (A.D.D.).

Hyperactive children are usually of normal intelligence, but they have difficulty sitting still and concentrating, and therefore may disrupt their families and create problems in school.

Many theories on the cause of hyperactivity have been developed, but none has been universally accepted. Some authorities believe that hyperactivity may be a symptom of several different problems that may have different causes.

At present, no fully effective treatment for hyperactivity exists. As a result, the condition is a terribly frustrating problem for its young victims, their parents, and their teachers.

In 1973, Dr. Benjamin Feingold, a California pediatric allergist, proposed that salicylates (naturally occurring substances present in many fruits, some vegetables, and a number of other foods), artificial food colors, and artificial flavors were causes of hyperactivity. He suggested a diet free of these substances for treatment and prevention of the condition.

Dr. Feingold presented his recommendations in two popular books,[1,2] and his ideas have received widespread media coverage. Many parents of children with behavior problems adopted the suggested diet, and some of them have reported a noticeable improvement in their children's behavior.

Since behavioral problems are complex, variable disorders that can be affected by many factors (including the power of suggestion), these parental observations must be interpreted cautiously. They are valuable because they suggest that a relation *might* exist between hyperactivity and certain food ingredients, and because they indicate that further investigation of this possible link would be worthwhile. But these informal observations alone cannot *prove* that this link exists.

To determine conclusively whether a substance affects behavior, carefully controlled scientific experiments must be performed. In the past six years, researchers have conducted several well-designed, controlled experimental tests of Dr. Feingold's theory and diet, involving hundreds of hyperactive children. In this report, the American Council on Science and Health briefly reviews these experiments and evaluates their results.

Position Statement

On the basis of its review of the scientific evidence, the American Council on Science and Health (ACSH) concludes that artificial food colors, artificial flavors, and the salicylate-containing foods specified by Dr. Feingold are *not* significant causes of hyperactivity in children. ACSH therefore does *not* recommend that these substances be eliminated or restricted in the diets of hyperactive children in an attempt to improve their conditions. Changes in food processing, food labeling, or food-related public policies in an effort to prevent or control hyperactivity in children are unwarranted.

The available evidence does not completely eliminate the possibility that a limited relationship might exist between certain food colors and hyperactivity. If this is so, however, it would affect only a very small number of hyperactive children.

ACSH also concludes that no physical harm is done by removing artificial flavors and colors from the diet. The placebo effect of these diet modifications and the changes in family dynamics associated with this dietary regimen may lead to behavioral improvement in some children. This potential benefit should be weighed against the potentially harmful long-term educational impact of communicating to a child that consumption of artificial colors and flavors controls behavior, when it does not.

The Feingold Theory

Dr. Feingold's ideas about the cause and treatment of hyperactivity have evolved and changed. His initial ideas were derived from his interpretation of research on aspirin intolerance in the early 1970s.

Aspirin (acetylsalicylic acid) is chemically similar to salicylate compounds that occur naturally in foods. Dr. Feingold proposed that hyperactivity is a symptom of salicylate intolerance in genetically predisposed individuals. He thought that this reaction might be biochemically similar to aspirin hypersensitivity. Because many aspirin-intolerant individuals

Some foods containing artificial colors and artificial flavors.

are also hypersensitive to tartrazine (Yellow food dye #5), Feingold suggested that this and other food colors could also cause hyperactivity. Noting that the chemical structures of several artificial flavors also resemble the salicylates, Feingold proposed that these substances too were involved.

Dr. Feingold presented his ideas in a popular book which recommended a diet that eliminated foods *he believed* to be high in salicylates, including many fruits and vegetables. All foods containing artificial (synthetic) colors or flavors were also forbidden.

In more recent publications, Dr. Feingold has revised his recommendations. He has de-emphasized the role of salicylates, and now allows salicylate-containing foods to be returned to the hyperactive child's diet after four to six weeks and continued thereafter if no adverse reactions occur. Artificial additives now receive the major emphasis. Besides artificial flavors and colors, Dr. Feingold now includes the antioxidant preservatives BHA (butylated hydroxyanisole) and BHT (butylated hydroxytoluene) on the list of forbidden food ingredients.

Based on his clinical observations and case reports (but not on controlled scientific experiments), Dr. Feingold has claimed that about half of the hyperactive children who strictly adhere to his diet recommendations show a marked reduction in hyperactive behavior, and that, of those who respond, two-thirds do so dramatically.

Rigorous scientific studies have not supported these claims. These studies are described later in this report.

Life on the Feingold Diet

Adherence to the Feingold diet causes abrupt changes in lifestyle and eating patterns. Most manufactured baked goods, luncheon meats, ice creams, powdered puddings, candies, soft drinks, and packaged and prepared foods are prohibited. Tea, coffee, and most commercially produced condiments are also excluded from the diet. Many non-food items such as mouthwash, toothpaste, vitamin pills, perfume, and some over-the-counter and prescription drugs are forbidden.

If the salicylate restriction is rigidly observed, many fruits and vegetables are prohibited, including most of the fruits that are rich sources of vitamin C. Parents who observe this restriction must plan meals carefully to make sure that their children receive enough of this vitamin.

Eating in restaurants and school cafeterias is practically impossible on the Feingold diet. Eating at home also becomes more difficult. Many convenience foods are prohibited because they contain artificial flavors and colors. Homemade foods, prepared "from scratch," become necessary for most family meals, including lunches carried to school.

Dr. Feingold strongly recommends including the hyperactive child in the preparation of the special foods and encourages the entire family to participate in the diet program. This is suggested in order to prevent the child from feeling different from the rest of the family at mealtimes, to reduce the temptation to cheat, and to provide the positive motivation of team involvement and a group goal. The food preparation and

total family involvement focus much attention on the hyperactive child, and require a substantial commitment of time and effort by the homemaker(s).

Family attitudes may also change when the Feingold diet is adopted. Since Dr. Feingold's theory blames food ingredients for the child's problems, some parents who accept the theory may cease to blame the child or themselves for hyperactive behavior.

All of these factors may enter into the positive response often reported by families who try the Feingold diet.

What Substances Does the Feingold Diet Eliminate?

Scientists have found it difficult to identify exactly what chemical substances the Feingold diet prohibits. Dr. Feingold is not a chemist, and his books include some inaccurate or ambiguous statements about food chemistry.

Identification of the prohibited artificial colors is easy. There are only nine of these, and the same substances do not occur naturally in foods. The more recent recommendation to eliminate BHA and BHT is equally clear, since these are two specific chemicals which are found in foods only as additives, not as natural constituents.

Artificial flavors, however, are a large and varied group of chemical substances. The chemical components of synthetic food flavors are usually identical to chemicals present in natural foods. Our bodies cannot distinguish between natural and synthetic substances which are chemically identical. Therefore, excluding artificial flavors from the diet, while permitting chemically identical natural food constituents, is scientifically irrational.

Dr. Feingold's identification of salicylate-containing foods has also created some confusion. There is little scientific information on the salicylate content of foods. In his first book, Dr. Feingold published a list of fruits and vegetables prohibited because they contain salicylates. After the book was published, research scientists determined the salicylate content of many fruits and vegetables.[3] They found that some foods allowed on the Feingold diet contained substantial amounts of salicylates, while some prohibited foods contained much smaller amounts. Some evidence indicates that salicylates may be present in *all* plants (and therefore all fruits and vegetables).[4] Thus, the published Feingold diet does not really eliminate salicylates.

The scientific validity of the parts of the Feingold theory involving artificial flavors and salicylates is questionable. Also, Dr. Feingold has emphasized food colors as the primary offending substances. For these reasons, experimental tests of the Feingold theory have focused on either 1) the diet regimen as a whole, or 2) artificial colors specifically.

Two experimental designs have been used to test the effect of the Feingold diet on hyperactivity: diet crossover studies, which test the effects of the diet regimen as a whole; and specific challenge experiments, which examine the effects of artificial food colors on behavior.

Diet Crossover Studies

In a diet crossover study, groups of hyperactive children are put on two different experimental diets. One group is placed on a diet that follows Dr. Feingold's recommendations. The other group's diet is disguised to look like the Feingold diet, but it actually contains forbidden food ingredients. The behavior of the children is observed while they are on each diet.

These experiments are called "crossover" studies because each group is tested on one diet, then switched to the other and tested again. In this way, the responses of each individual child to the two diets can be compared.

Neither the child nor the persons observing and testing behavior are told which group the child belongs to. This is called a "double-blind" study because both the subjects and the observers are "blind" to the subject's group assignment.

In the two major diet crossover studies that have been completed,[5,6] parents, teachers, and trained observers watched and recorded the children's behavior. In some cases, tests of learning ability and other psychological measures that may be related to hyperactivity were also performed.

The diet crossover studies have proved to be difficult to carry out and evaluate. They also have proved to be very expensive. Overall, the results were inconsistent and difficult to interpret.

The problems encountered in these studies included the following: In some cases parents reported mild, subjective behavior changes, but learning and psychological tests did not confirm these changes. Some families may have been able to figure out which diet was really the Feingold diet. If they did "break the code" this could greatly affect the results. Some behavior changes were observed only when the diets were tested in one order, but not when the order was reversed. Also, in one study parents seemed to detect behavior changes while teachers didn't. The other study yielded opposite results; teachers noted changes that parents did not report.

Because of these difficulties, definite conclusions about the effectiveness or ineffectiveness of the Feingold diet could not be reached on the basis of the diet crossover studies. The investigators went on to carry out a second type of study—specific challenge experiments.

Specific Challenge Experiments

For a specific challenge experiment, the investigator selects hyperactive children who have apparently responded to the Feingold diet with a reduction in hyperactive behavior, either in an earlier diet crossover study or in unsupervised use of the diet by their families. The children are assigned to two groups. Both groups are given a diet that meets the Feingold guidelines. One group also receives a special test food that appears to meet the guidelines, but actually contains artificial colors. The other group receives a control food that looks and tastes exactly the same, but contains no artificial color. The behavior of both groups is observed, tested, and evaluated. Usually, there is also a second testing period in which the group assignments are reversed, so that the responses of each child to the test and control food can be compared.

As with the diet crossover studies, these experiments must be conducted in "double-blind" fashion.

Seven specific challenge experiments, involving about 190 children, have been completed. Six of these yielded generally similar results. The seventh study differed; it will be discussed separately.

In the first six studies,[7-12] consistent dramatic deteriorations in behavior did *not* occur when the children were fed the artificial colors under double-blind conditions. This was true even when the amount of food color administered substantially exceeded the average daily consumption level of an American child. Although the children had been selected for the experiments because their behavior improved when they were placed on the Feingold diet under non-blind conditions, they demonstrated little or no response to artificial colors in the controlled, double-blind experiments.

In a few cases (3 out of more than 150), parents reported mild behavioral changes when the artificial colors were administered. In two of these three cases, other observers or objective tests were available, and they did not confirm the parental observations.

Since evidence to confirm the parental observations is, unfortunately, lacking, these three cases cannot be regarded as definite proof that a genetically determined sensitivity to food colorings exists. If it does exist, it must be very rare. All of the children tested in these studies were apparent responders to the Feingold diet. Of this highly selected group, only two percent actually showed a response to food colors under controlled conditions. An even smaller percentage of responders would be expected in an unselected group of hyperactive children.

The generally negative findings in these experiments contrast sharply with the high percentage of positive behavior changes reported by Dr. Feingold and others who use the special diet

under scientifically uncontrolled conditions. It is particularly significant that the *same* children who respond to the regimen under non-blind conditions do not respond to food colors in controlled experiments. This suggests that factors other than the actual diet modifications cause the behavior improvements widely reported by parents.

In the seventh specific challenge experiment,[13] two Toronto researchers fed very large doses of food colors, in capsule form, to children with behavior problems. After the children consumed the color capsules or identical-looking placebo capsules that contained no colors, they were given a laboratory learning test.

The total group of children was divided into more symptomatic and less symptomatic groups. The researchers claimed that the more symptomatic group showed deterioration of their performance on the test after the color capsules were administered, but not after the placebo capsules were given. The less symptomatic group's performance was unaffected by the capsules.

The implications of these findings remain unclear. Are the laboratory test scores an accurate reflection of behavior at home and in the classroom? How are children in the two groups different? Does a study that measures behavior after administration of a large dose of pure food color in capsule form mimic what happens when usual amounts of color are consumed, in foods, over the course of a day? Further research is needed to clarify these issues.

In addition, several scientists have strongly questioned this study on technical grounds.[14-16] They have suggested that the experimental data may not justify the conclusions reached by the original researchers. The critics have pointed out that while the performance of the two groups differed, this was largely because the two groups performed differently after consuming the *placebo* (color-free) capsule. This is readily seen in the published report of this study* and is unexplained. The scientists who have criticized this study believe, and ACSH agrees, that because of this anomaly, no definite conclusion can be reached from this experiment. Further research of this type would be valuable, so that the effects of large doses of food colors can be unambiguously determined.

Food Additives and Hyperactivity: A Perspective

These experiments show that artificial food colors, artificial flavors, and the "salicylate-containing" foods specified by Dr. Feingold do not have the dramatic impact on hyperactivity that he predicted. In light of this evidence, the reports that children on this diet have improved dramatically must be cautiously evaluated.

The Feingold diet is not merely a food plan; it is a way of life. Adoption of this regimen leads to substantial changes in family activities and attitudes. It is possible that these circumstances, rather than the diet changes themselves, might cause a reduction in hyperactivity.

*See Figure 1 in Reference 13.

Many parents who try the Feingold diet have high hopes for its success. These positive expectations may also lead to reports of improved behavior.

Because the Feingold diet does no physical harm, it might be helpful therapy in some instances due to its impact on the family. The potential benefits, however, must be weighed against the potentially harmful impact of teaching a child to "blame" food ingredients for his difficulties when other factors are more likely to be responsible.

ACSH also believes that the spread of inaccurate health information is inherently undesirable. While the Feingold diet will not harm an individual hyperactive child, public acceptance of the idea that it is "the answer" to hyperactivity, when it is not, could be very harmful to the community as a whole. For instance, it could discourage research on other, more promising, theories about hyperactivity.

Dr. Feingold and others who accept his theory have proposed substantial changes in child feeding practices and food-related public policies. They have recommended legislation that would require the use of a special symbol on food labels to signify that no synthetic colors or flavors are present in the product. Dr. Feingold has also recommended that federally subsidized school lunch programs exclude additive-containing foods.

The scientific tests of the Feingold diet indicate that these expensive public policy changes are unnecessary. Unfortunately, in many communities, individuals who are unaware of the current status of the Feingold theory are still promoting these costly changes, particularly in school feeding programs.

Hyperactivity will continue to be a frustrating problem until research resolves the question of its cause, or causes, and develops an effective treatment. We still have a great deal to learn about this condition.

If Your Child Has Behavior Problems

If your child has behavior problems or difficulties in school, you need reliable information on the nature of your child's problem, and on the best way to deal with it. Not all behavioral disorders are related to hyperactivity, and not all can be dealt with in the same way. If your family faces this type of problem, ACSH's mental health consultants recommend that you ask your pediatrician or family physician to refer you to a child psychiatrist or psychologist, or to a mental health clinic that works with children. These professionals can help to identify the type of difficulty your child is having, and recommend practical ways to deal with it.

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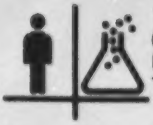

1995 Broadway
(near 68th Street)
New York, NY 10023
Telephone: 212 362 7044

1111 19th Street, N.W.
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Telephone: 202 659 8978

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and Occupational Epidemiology

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Media Specialist

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